UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, a corporation,	)	Docket No. 9297
and	)	
American Home Products Corporation, a corporation	)	

RESPONDENT SCHERING-PLOUGH CORPORATION'S STATEMENT OF THE CASE INVOLVING SCHERING AND UPSHER-SMITH

Pursuant to the Court's Scheduling Order, respondent Schering-Plough Corporation ("Schering") submits this statement of the case with respect to the settlement and license agreement between Schering and Upsher-Smith Laboratories ("Upsher" or "Upsher-Smith").

A. Introduction

Schering manufactures and sells the brand name drug K-Dur®, a sustained-release potassium chloride tablet. K-Dur® is made in conformity with Schering's Patent No. 4,863,743 (the "'743 patent"), which claims a novel formulation for a sustained-release potassium chloride tablet. Schering's patent does not expire until September 2006.

In late 1995, Upsher-Smith notified Schering that it had filed an Abbreviated New Drug Application ("ANDA") seeking approval to market its sustained-release potassium

chloride product as bioequivalent to Schering's K-Dur®. Schering brought a patent infringement suit against Upsher, alleging infringement of Schering's '743 patent.

After discovery had largely concluded and as the trial date was approaching, the parties engaged in settlement discussions. The parties discussed a settlement under which Schering would grant Upsher a license to market its product for part of the life of Schering's patent. Schering had flatly rejected the idea that it should pay money to Upsher as part of a settlement. One week before trial no settlement had been reached. Upsher then offered to sell Schering the rights to market, outside the United States, Niacor-SR, a product which Upsher had in development. Niacor-SR was a sustained-release niacin product for treatment of elevated cholesterol. This offer was of significant interest to Schering, which had recently tried, unsuccessfully, to acquire rights to a very similar sustained-release niacin product from another company.

Two Schering officials, who were not made aware of the patent lawsuit, evaluated the proposed Niacor SR license and concluded that it was worth more to Schering than the price Upsher was asking.

Schering and Upsher then successfully settled the patent infringement lawsuit, the day before trial, by compromising on the remaining life of Schering's patent. Thus, although Schering's patent does not expire until September 2006, the settlement agreement (the "Upsher Settlement") grants Upsher a royalty free license under Schering's patent to bring its generic K-Dur® product to market in September 2001, five years before expiration of the '743 patent. Upsher's product is now on the market. In conjunction with the settlement, Schering and Upsher entered into a licensing transaction in which Upsher gave Schering licenses to market outside the United States four products, including Niacor-SR, the sustained-release niacin product. In exchange for the licenses, Schering made an up-front royalty payment of $28 million, followed by additional payments of $20 million and $12 million.

Complaint Counsel challenge this settlement principally on the ground that, in their judgment, the rights to Niacor-SR were not worth what Schering paid. Complaint Counsel allege that the payments Schering made for the rights to Niacor-SR were really disguised payments to induce Upsher to agree to keep its generic version of K-Dur off the market for a few years.

There is, of course, no direct evidence to support this. Complaint Counsel relies principally on an expert report in which the expert, using hindsight, downgrades the value of Niacor-SR, criticizes Schering's due diligence in evaluating the Niacor-SR license, and arrives at an "expert" opinion regarding Schering's intent.

As Schering is prepared to show, however, the price it paid for the Niacor-SR license was objectively reasonable; it was in no way a subterfuge; and it permitted the parties to settle the patent litigation on terms that were very favorable to consumers and to competition.

1. Settlements Are Beneficial

The law strongly favors the settlement of disputes. *See, e.g., D.H. Overmyer Co. v. Loflin*, 440 F.2d 1213, 1215 (5th Cir. 1971) ("Settlement agreements are highly favored in the law and will be upheld whenever possible. . . ."); *In re Sumitomo Copper Litig.*, 869 F.2d 1469, 1473 n.5 (Fed. Cir. 1989) ("The arm's-length compromise of a disputed claim has long been favored by the courts."); *Hartley v. Mentor Corp.*, 869 F.2d 1469, 1473 n.5 (Fed. Cir. 1989) ("[The] position that the courts should favor and enforce settlement agreements is one this panel heartily endorses."). Settlements allow the parties to save huge litigation costs. They permit parties to avoid the distraction of corporate officials that inevitably accompanies litigation. They permit businesses to plan, with some certainty, about businesses' future. And they permit the parties to avoid the risks and uncertainty associated with a trial. All of these cost savings will inevitably be passed on to consumers by American businesses. For these reasons, settlements are much more likely to benefit consumers than the alternative of continued litigation. Moreover,

settlements preserve scarce judicial resources, as well. Schering will offer expert testimony from two expert witnesses, one a renowned law professor on the subjects of negotiation and dispute resolution, and the other a practitioner with experience as a litigator and mediator of patent disputes, to support these points.

Schering's experts will also testify that exploring business transactions outside the matters in litigation is a normal and recommended way of settling difficult legal disputes. Such transactions facilitate the settlement of intractable disputes because they permit both parties to obtain positive benefits from the resolution of the dispute. One of Schering's experts has written a book and teaches classes on this settlement technique. The other expert uses it in his mediation work.

2. The Niacor-SR License Was Not a Sham

Schering will prove that the Niacor-SR license agreement is a good example of parties seeking to resolve a dispute by exploring other business opportunities outside the products involved in the dispute. As set forth above, Upsher offered Schering during the settlement negotiations the opportunity to license Niacor-SR, a sustained-release niacin product. Schering had a documented and preexisting interest in sustained-release niacin, and had negotiated with another company, Kos Pharmaceuticals ("Kos"), for the right to co-market its sustained-release niacin product. Schering was interested in such a product in part because it would permit Schering to develop expertise and relationships in the cholesterol-lowering market in advance of the launch of Schering's principal pipeline product, ezetimibe, which is a cholesterol-reducing product.

Niacin is a well-known, well-characterized drug, which is unique among cholesterol-lowering drugs in that it reduces the level of "bad" cholesterol, triglycerides, and other factors linked to heart disease, while simultaneously elevating the level of "good" cholesterol. It had not been successful in immediate-release formulations principally because it had an unpleasant side effect, in that it caused patients to experience uncomfortable flushing sensations. Flushing is not a health risk, but it is

unpleasant and as a result patients are reluctant to take immediate release niacin. The concept behind sustained-release niacin was to reduce flushing while retaining niacin's efficacy. Upsher's clinical trial results with Niacor-SR were consistent with this expectation.

When Upsher raised the possibility during the course of settlement negotiations of a Niacor-SR license, Schering sought the views of James Audibert. Mr. Audibert, who has a master's degree in pharmacology and who currently works in Schering's research division, Schering-Plough Research Institute, was intimately familiar with sustained-release technology. He had personally worked on a number of products consisting of old and effective drugs, hampered by undesirable side effects, which became financial and medical successes through use of sustained-release technology. Mr. Audibert had years of experience in reviewing data from clinical trials of sustained-release formulations of such products. In addition, Mr. Audibert was intimately familiar with the cholesterol reducing market, having studied it in connection with his responsibilities for ezetimibe. As a member of Schering's global marketing group, Mr. Audibert was also familiar with the relevant markets outside the United States. He had also been involved in Schering's evaluation of Kos' similar niacin product.

Mr. Audibert, who was *unaware* of the patent litigation, reviewed the information concerning Upsher's clinical trials and did a written financial assessment of the proposed Niacor-SR license. His work was reviewed by Thomas Lauda, who was the executive vice-president in charge of Global Marketing, and who was also unaware of the patent lawsuit. Mr. Lauda concluded that the license rights to Niacor-SR were worth considerably more than Upsher was asking.

Schering will offer testimony by outside experts who have reviewed the Upsher clinical trial information that the Niacor-SR license, judged as of June 1997, was worth more than Schering paid for it.

Mr. Audibert's and Mr. Lauda's view of the prospects for a sustained-release niacin product was shared by the marketplace. In the months before Schering and Upsher entered into the settlement and license agreement, Kos, a one-product company, had a market capitalization of over $400 million, based almost entirely on the sales expectations for its sustained-release niacin product. Market analysts predicted that the Kos product would have annual sales in the United States in excess of $200 million. In addition, Schering's own somewhat more conservative contemporaneous evaluation of the Kos product was that the likely sales of Kos' sustained-release niacin product had a net present value of $420 million.

Kos' product did not sell well when it actually came to market in the fall of 1997, after Schering's settlement with Upsher; and Kos' stock price fell by over 80 percent. Thus, in the fall of 1998, when Schering was faced with the question whether to proceed with further investments to pursue regulatory approval of Niacor-SR, the prospects for sustained-release niacin looked considerably dimmer than they had when Schering entered into the license agreement. Schering therefore decided not to pursue it.

3. The Settlement Was Reasonable and Beneficial to Consumers in Light of Schering's K-Dur® Patent

Schering will prove that its settlement with Upsher, pursuant to which Upsher is now on the market with a generic product, is procompetitive. The settlement permitted generic competition to K-Dur® five years before expiration of Schering's patent. Experts will testify that Upsher could not have marketed its product until after 1999 even if it had won the patent case. Experts will also testify that given the strength of Schering's patent, settlement was better for consumers (and competition) than taking their chances on the outcome of litigation would have been. Thus, the settlement, which provided for *certain* entry five years before patent expiration, was procompetitive, not anticompetitive.

4. The Impact of Hatch-Waxman's Exclusivity Provisions is Unclear and is Not Attributable to Schering

Schering will show that at the time it entered into the settlement with Upsher, it was reasonable to conclude that the settlement would deprive Upsher of any so-called 180-day exclusivity rights it might have had, and that under the settlement, Upsher would *not* block other generics from entering the market for the first 180 days. An FDA regulation then in effect provided that a first filer was only entitled to block subsequent filers if it "successfully defended" its patent case. This regulation was withdrawn *after* the settlement (in 1999), raising the possibility that FDA would regard Upsher as having the ability to block other generics. But even then, Upsher still had the right to transfer whatever rights it had to others -- the settlement agreement, unlike some challenged by the Commission previously, did not contain terms precluding Upsher from transferring any exclusivity rights to third parties.

At the present, it is unclear whether Upsher blocks other generics from the market. Schering, had it chose to do so, would have been privileged under *Noerr-Pennington* to lobby the courts and agencies on this issue. But Schering had nothing whatsoever to do with these arguable changes in the law, and it cannot be held liable for them under the antitrust laws.

B. Legal and Factual Issues to be Decided by the Administrative Law Judge

1. Whether the Upsher/Schering Agreement is Reasonable

The overarching issue to be resolved with respect to the Upsher/Schering agreement is whether that agreement imposes an unreasonable restraint on competition. That issue is to be analyzed under the rule of reason. *See, e.g., State Oil Co. v. Khan,* 522 U.S. 3, 10 (1997) (most antitrust claims involved an analysis of whether the questioned practice imposes an unreasonable restraint on competition). Courts will depart from this standard inquiry into reasonableness when extensive experience with a specific type of restraint has shown that anticompetitive effects of the restraint almost always outweigh its procompetitive benefits. *See, e.g., Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S.

36, 49-50 & n.16 (1977); *Broadcast Music Inc. v. Columbia Broadcasting Sys., Inc.* 444 U.S. 1, 19-20 (1979); *Khan*, 522 U.S. at 10; *Walker Process Equip., Inc. v. Food Mach. Corp.*, 382 U.S. 172, 178 (1965).

Settlements of intellectual property litigation in particular should be analyzed under the rule of reason. Courts have limited experience in evaluating such agreements, and, as set forth above, settlements provide important procompetitive benefits that must be taken into consideration in any antitrust analysis. *See, e.g., Speed Shore Corp. v. Denda*, 605 F.2d 469, 473 (9th Cir. 1979) (court must balance "deeply-instilled policy of settlement[s] against claim that patent settlement unreasonably restrained trade"); *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir, 1976) (same). The Commission's ongoing generic drug competition industry survey, designed to provide the Commission with more information about these types of agreements, demonstrates that it currently lacks sufficient experience in analyzing patent infringement settlement agreements to condemn any particular one as unreasonable *per se*.

2. Whether the Niacor-SR License Was a Sham

The Court will have to determine whether the Niacor-SR licensing transaction, judged at the time it was entered into, was a sham or subterfuge designed to disguise a payment to Upsher to refrain from marketing its potassium chloride product.

3. Whether the Split in the Patent Life Under the Settlement Reflects the Strength of Schering's Position in the Lawsuit

In order to determine whether the Upsher/Schering settlement was reasonable, the Court will have to determine whether its terms, which guaranteed generic entry five years before expiration of Schering's patent, were more or less beneficial to consumers than what would have occurred had the settlement not been reached. Put another way, the Court must compare the effect on consumers of the settlement agreement to the "but for" world of continued litigation. If the settlement (*i.e.*, the split in the remaining patent life)

reflects the objective strength of the parties' positions in the underlying patent litigation, then no consumer harm can result from a settlement that permits Upsher to market its product at a time that reflects its chances in prevailing in the litigation.

4. Whether, at the Time of the Upsher/Schering Settlement, Upsher Was Entitled to Exclusivity Under FDA Rules

The Court may have to resolve whether, at the time Upsher and Schering settled, Upsher was entitled to block entry of other generics under FDA rules. The Court may have to determine whether Upsher, if it was not so entitled at the time of the settlement, became entitled to block them at some point subsequent to the settlement. If so, the Court will have to determine whether that entitlement was caused by Schering and Upsher, or whether it was caused by the FDA or the courts. Finally, the Court will have to resolve the question whether Schering, under the *Noerr-Pennington* doctrine, can be held liable under the antitrust laws for the effects of legal rules developed by Congress, FDA, and the Courts.

5. Whether the Upsher/Schering Settlement Prevents Upsher from Marketing Non-infringing Products

The Complaint alleges that the Upsher/Schering settlement prevents Upsher from marketing not only its generic K-Dur®, but also from marketing other similar products that did not infringe. The analysis of this issue will require an evaluation of whether the intention of the agreement was to prevent only the marketing of products that presented substantially the same infringement issue as Upsher's generic K-Dur® product. It will also require the Court to determine whether Upsher had the ability and intent to manufacture a non-infringing product that would compete with K-Dur®.

6. Whether the Matter is Moot

As part of the relief requested in this matter, the complaint seeks an order requiring Schering to "immediately license for no compensation its '743 patent to

Upsher-Smith . . . so as to allow [Upsher] to make, produce, and market commercially generic versions of Schering's K-Dur 20 and K-Dur 10." Complaint, Notice of Contemplated Relief ¶ 5. Pursuant to the terms of the settlement, Upsher-Smith's generic equivalent of K-Dur 20 entered the market at the beginning of this month. Thus, the prospective relief sought by Complaint Counsel against Schering has been implemented by virtue of the settlement itself. This would seem to make the matter moot.

C. Status of Compliance with Discovery

Schering produced approximately 100 boxes of materials during the year-and-a-half investigation of this matter. Schering is in the process of producing documents in response to Complaint Counsel's post-complaint requests. These include approximately 20 boxes of documents that will be produced by the end of this week related to Schering's ezetimibe. Schering is negotiating with Complaint Counsel regarding Complaint Counsel's very broad requests for documents related to licenses and evaluations of other products not involved in the Upsher or ESI settlements.

Schering continues to produce documents in response to Complaint Counsel's document requests, and has reached agreements with Complaint Counsel regarding dates for compliance with certain of those requests.

Complaint Counsel has taken a number of Schering depositions in this litigation and the pre-complaint investigation. Schering is continuing to work with Complaint Counsel to schedule additional depositions requested by Complaint Counsel.

Schering served requests for documents on Complaint Counsel on or about June 19, 2001. Complaint Counsel has produced certain materials gathered during its lengthy investigation of this case, and has produced about two boxes of documents in response to Schering's document requests.

In early June 2001, Schering filed a Freedom of Information Act ("FOIA") request with the Food and Drug Administration ("FDA") for certain documents. While FDA has

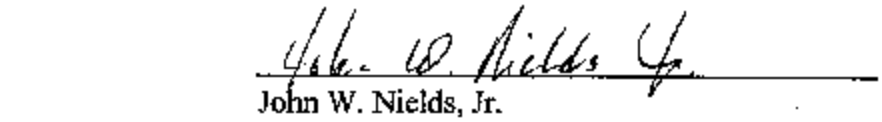
not yet produced any documents in response to the request, Schering continues to work with FOIA staff at FDA to obtain such materials.

Schering has issued a number of interrogatories to Complaint Counsel. Most of these are "contention" interrogatories that ask Complaint Counsel whether it is taking certain positions and, if so, what facts on which intends to rely at the hearing in support of them. Complaint Counsel has for the most part declined to state what facts it intends to rely upon, on the ground that it is premature to do so before the close of discovery.

D. Status of Settlement Negotiations

There are no ongoing discussions between Schering and Complaint Counsel regarding the settlement of this matter. Schering remains willing to confer with Complaint Counsel in good faith regarding a negotiated resolution of this case.

Respectfully submitted,



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Dated: September 18, 2001

Attorneys for Respondent
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CERTIFICATE OF SERVICE

I hereby certify that this 18th day of September, 2001, I caused an original, one paper copy and an electronic copy of the foregoing Respondent Schering-Plough Corporation's Statement of the Case Involving Schering and Upsher-Smith to be filed with the Secretary of the Commission, and that two paper copies were served by hand upon:

Honorable D. Michael Chappell
Administrative Law Judge
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